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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/873,224	06/05/2001	Geert Maertens	2752-45	4458

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EXAMINER
MARTINELL, JAMES

ART UNIT	PAPER NUMBER
1631	5

DATE MAILED: 04/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/873,224	MAERTENS ET AL.	
	Examiner	Art Unit	
	James Martinell	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 November 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-57* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *6/5/01* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The references crossed out on form PTO-1449 were not considered because no copies of those references are in this or the parent files.

The instant application should contain a section entitled "Brief Description of the Drawings".

Content of Specification

(a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data shet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.

(b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.

(c) Statement Regarding Federally Sponsored Research and Development: See MPEP § 310.

(d) Incorporation-By-Reference Of Material Submitted On a Compact Disc: The specification is required to include an incorporation-by-reference of electronic documents that are to become part of the permanent United States Patent and Trademark Office records in the file of a patent application. See 37 CFR 1.52(e) and MPEP § 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text were permitted as electronic documents on compact discs beginning on September 8, 2000.

Or alternatively, Reference to a "Microfiche Appendix": See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.

(e) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:

(1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."

(2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."

(f) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive

concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

(g) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.

(h) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.

(i) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet (37 CFR 1.52(b)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).

(j) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

(k) Sequence Listing, See 37 CFR 1.821-1.825 and MPEP §§ 2421-2431. The requirement for a sequence listing applies to all sequences disclosed in a given application, whether the sequences are claimed or not. See MPEP § 2421.02.

The disclosure is objected to because of the following informalities.

(a) The recitation of "hybridisation" at the following locations should be changed to "hybridization": claim 36, lines 2 and 3; claim 37, lines 2 and 3; claim 38, line 2; and claim 39, line .

(b) The instant application does not comply with the Sequence Rules (37 CFR §§ 1.821-1.825) in that sequences appear in Table 6, page 70 without SEQ ID NOs.

Appropriate correction is required.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). A properly executed oath or declaration which complies with 37 CFR 1.67(a) and identifies the application by application number and filing date is required. Such alterations appear in the Sequence Listing at page 197 between the last two lines and in Figure 1, page 4/111, under the line listed as "BE98".

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 26, 28, 30-40, 42, 44, 46, 48, and 50-57 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague, indefinite, incomplete, misdescriptive, and inaccurate for the following reasons.

(a) The recitation of "genotype-specific" (claim 24) is vague and indefinite because the term is not defined in the application.

(b) The recitation of "polynucleic acid is capable of acting as a primer for specific amplification for HCV type- or subtype-specific amplification" (claims 32 and 33) is vague, indefinite, and incomplete because the instant application does not teach or disclose the minimum size for such primers that have the claimed properties.

(c) The recitation of "polynucleic acid is capable of acting as a primer for specific amplification of a HCV subtype 3c nucleic acid sequence" (claims 34 and 35) is vague, indefinite, and incomplete because the instant application does not teach or disclose the minimum size for such primers that have the claimed property.

(d) The recitation of "polynucleic acid is capable of acting as a probe for specific hybridisation to a HCV type or subtype-specific hybridisation" (claims 36 and 37) is vague, indefinite, and incomplete because the instant application does not teach or disclose the minimum size for such primers that have the claimed properties.

(e) The recitation of "polynucleic acid is capable of acting as a probe for specific hybridisation to a HCV subtype 3c nucleic acid sequence" (claims 38 and 39) is vague, indefinite, and incomplete because the instant application does not teach or disclose the minimum size for such primers that have the claimed property.

(f) Claims 50-57 are misdescriptive because the preamble recites "A kit", but only method steps follow. Thus, the claims are not drawn to kits at all.

(g) The recitation of "possibly" (claims 54-57) is vague and indefinite. The substitution of "optionally" for "possibly" is suggested.

(h) The recitation of "appropriate conditions" (claims 54-57) is vague, indefinite, and incomplete because the claims do not mention for what the conditions are to be appropriate nor does the application distinguish between appropriate conditions and inappropriate conditions.

Claims 24-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants do not point to the basis in the application as filed for any of the limitations in new claims 24-57 added by amendment (paper no. 3). Thus, the claims are deemed to contain New Matter.

For example, there is no teaching in the application as filed for probes or primers that are 8 nucleotides in length. The date of submission of the amendment (paper no. 3) is not clear. Paper no. 3 bears a date of June 5, 2001 and no other date. However, paper no. 3 mentions an attached PTO-1449. The only PTO-1449 in the file was received in the USPTO on November 20, 2002. Thus, it is presumed that the date paper no. 3 was received in the USPTO was November 20, 2002.

Claims 24-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant application does not teach one of skill in the art how to make and use oligonucleotide probes or primers with the claimed properties of specificity of hybridization. The use of long probes will not provide specific hybridization because of the increasing stabilization resulting from the sequences that the various HCV types and subtypes have in common as is evidenced by the Figures in the application. The application does not teach the use of probes or primers as short as 8 nucleotides for specific hybridization to HCV DNA sequences. Wallace et al (Methods Enzymol. 152: 432 (1987) teaches that probes shorter than 14 bases long are not suitable for specific hybridization to DNA. For example, at pages 433-434, Wallace et al states: "Oligonucleotides have a tendency to bind nonspecifically to noncomplementary DNA sequences. This is probably due to an unavoidably low degree of homology of short oligonucleotides to other DNA sequences and is a particular problem with probes shorter than 14 bases long." In addition, the instant application does not teach one of skill in the art how to amplify specific DNA sequences using only one primer (Claims 50-57).

Claims 24-57 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The application does not provide an adequate written description of the claimed invention because no probes with the described desired properties are described. The discussion in the rejection immediately above is incorporated here.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (WO 92/19743 (November 12, 1992)) in view of Wallace et al (Methods Enzymol. 152: 432 (1987)). Cha et al discloses a HCV DNA that shares 43 nucleotides with SEQ ID NO: 147 of the instant application. SEQ ID NO: 60, positions 212-254 of Cha et al are identical to SEQ ID NO: 147, positions 211-253 of the instant application. Wallace et al teaches the construction and use of hybridization probes for the specific detection of nucleic acids. It would have been obvious for one of ordinary skill in the art at the time the invention was made to make and use oligonucleotide probes to any region of the DNA disclosed in Cha et al in the manner taught by Wallace et al in order to detect nucleic acids.

Claims 28-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cha et al (WO 92/19743 (November 12, 1992)) in view of Wallace et al (Methods Enzymol. 152: 432 (1987)) as applied to claims 24 and 25 above, and further in view of applicants' admitted state of the prior art (instant application at page 24). Applicants acknowledge various amplification procedures to be old. It would have been further obvious for one of ordinary skill in the art to amplify the nucleic acids in the manner

admitted to be old. In addition, it would have been obvious for one of skill in the art to assemble the various reagents needed to perform the above-mentioned procedures into a kit for mere convenience (claims 50-57).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James Martinell whose telephone number is (703) 308-0296. The fax phone number for Examiner Martinell's desktop workstation is (703) 746-5162. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be e-mailed to james.martinell@uspto.gov. Since e-mail communications may not be secure, it is suggested that information in such requests be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (703) 305-4028. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

James Martinell, Ph.D.
Primary Examiner
Art Unit 1631